

Application No. 09/921,844
Amendment dated June 15, 2009
Reply to Final Office Action of December 15, 2008

REMARKS

Applicant added new dependent claims 285 and 286 to further define Applicant's claimed invention. Support for new claims 285 and 286 can be found at least in FIGS. 12, 13, and 15. No new matter has been added.

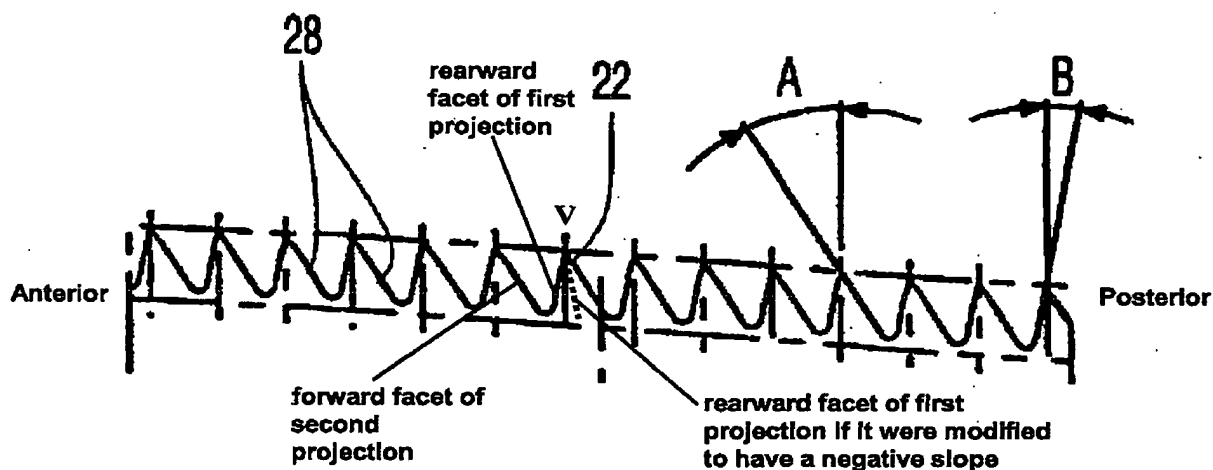
In the Office Action, the Examiner objected to the amendments to the specification filed October 9, 2007 under 35 U.S.C. § 132(a) as introducing new matter into the disclosure. Applicant respectfully disagrees with the Examiner's contention that the "added material which is not supported by the original disclosure is as follows: an included angle that is larger than 90 degrees." (Office Action, page 2, lines 15-17.) Applicant's FIG. 14 shows that rearward facet 326 includes a perimeter, which from the end view shown in FIG. 14 is in the shape of a triangle. The perimeter of rearward facet 326 has a first side and second side being in a convergent relationship to each other and having an included angle greater than 90 degrees therebetween. As shown in FIG. 14, converging sides of the perimeter of rearward facet 326 have only one included angle greater than 90 degrees therebetween. Nonetheless, in order to expedite the prosecution of this application, Applicant amended the specification to remove the language objected to by the Examiner.

The Examiner rejected claims 1, 3, 5, 19-51, 203, 204, 207-209, 219, 228-254, 259-271, and 277-284 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,482,233 to Aebi et al. ("Aebi") in view of U.S. Patent No. 6,592,624 to Fraser ("Fraser"). Applicant respectfully traverses the rejection at least for the reason that the combination of Aebi and Fraser does not result in Applicant's claimed invention as recited in independent claims 1 and 219.

Independent claim 1 recites a spinal implant comprising at least a first and a second surface projection formed on its upper and lower surfaces, the projections each having a forward facet and a rearward facet, "the slope of said rearward facet being steeper than the slope of said forward facet," and "at least a portion of said rearward facet of said first surface projection overlying a portion of said forward facet of said second surface projection." Applicant respectfully disagrees with the Examiner's

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contention that "with the rearward facet having a negative slope, the adjacent projections of Aebi [sic] et al would produce 'at least a portion of said rearward facet of the first surface projection overlying a portion of said forward facet of said second surface projection.'" (Office Action, page 4, lines 3-6.) Independent claim 1 does not recite a rearward facet having a negative slope. The slope of the rearward facet is steeper than the slope of the forward facet. FIG. 6 of Aebi is partially reproduced and annotated below for the Examiner's reference.



The dotted line in the above illustration represents a hypothetical example of a rearward facet of the first surface projection of Aebi having a negative slope relative to the vertical (V) as proposed by the Examiner. The illustration shows that even if the rearward facet of the first surface projection were to be modified to have a negative slope contrary to the teachings of Aebi, no portion of the rearward facet of the first surface projection would overlie a portion of the forward facet of the second surface projection as recited in independent claim 1. Moreover, this relationship is further emphasized by the fact that vertical line (V) itself does not overlie a portion of the forward facet of the second projection. Thus, Applicant submits that the combination of Aebi and Fraser as proposed by the Examiner does not result in an implant as recited in independent claim 1.

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Independent claim 219 recites an implant comprising surface projections, each of the surface projections including a "forward facet having a maximum length as measured along a line parallel to the maximum length of said base, the maximum length of said forward facet being greater than the maximum length of said base," the forward facet "having a perimeter with a first side and a second side, said first and second sides of said perimeter being in a convergent relationship and having a second included angle therebetween proximate said peak." The Examiner admitted that Aebi is "silent regarding the length of the forward facing facet having a maximum length as measured along a line parallel to the maximum length of the base, the maximum length of the forward facet greater than the maximum length of the base." (Office Action, page 3, lines 16-19.)

FIG. 1A of Fraser shows that triangular projection 18 has three facets, namely, a rearward facet 34 and two opposed side facets 30, 32 converging at crest 36. Contrary to the Examiner's contention, crest 36 of Fraser is not a forward facet as recited in independent claim 219 at least because it does not have "a perimeter with a first side and a second side, said first and second sides of said perimeter being in a convergent relationship and having a second included angle therebetween proximate said peak" of the projection. Thus, similarly to Aebi, Fraser does not disclose or suggest a forward facet as recited in independent claim 219. Accordingly, the combination of Aebi and Fraser does not teach or suggest each and every recitation of independent claim 219.

Applicant respectfully submits that contrary to the Examiner's contention, it would not have been "obvious to one of ordinary skill in the art to have formed the rearward facet of Aebi [sic] et al forming a negative slope . . . such that the projections dig into the bone and better resist expulsion." (Office Action, page 3, line 22 through page 4, line 1.) According to the Supreme Court, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". (KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007) (quoting In re Kahn, 441, F.3d 977, 988 (Fed Cir. 2006))). Applicant submits that

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Examiner's proposed modification of the rearward facet of spike 28 of Aebi in view of Fraser to have a negative slope lacks a rational underpinning to support the legal conclusion of obviousness.

Specifically, Aebi teaches that spikes 28 "are slanted toward the anterior end" and "in this arrangement provide rotational stability to the implant 10 and, thus, are less likely to rotate after insertion because each point of the spike 28 penetrates the opposing vertebrae." (Aebi, col. 4, lines 30-31, 59-62) (emphasis added). Aebi further teaches that the "orientation of the spikes is also designed for ease of insertion and to prevent retropulsion or dislodgement." (Aebi, col. 4, lines 62-64) (emphasis added). Applicant submits that since Aebi expressly teaches that spikes 28 already penetrate opposite vertebrae and prevent retropulsion or dislodgement, there would be no reason for one of ordinary skill in the art to change the configuration of the rearward facet of the projections of Aebi in view of Fraser "such that the projections dig into the bone and better resist expulsion" as contended by the Examiner. Thus, applicant submits that it would not have been obvious to one of ordinary skill in the art to modify Aebi in view of Fraser.

Independent claim 219 further recites "said first and second sides of said perimeter being in a convergent relationship and having a first included angle therebetween proximate said peak, said forward facet having a perimeter with a first side and a second side, said first and second sides of said perimeter being in a convergent relationship and having a second included angle therebetween proximate said peak, said first included angle being greater than said second included angle." Neither Aebi nor Fraser, taken alone or when properly combined, disclose or suggest such structure. In Aebi, the included angle at the peak of the forward facet is identical to the included angle at the peak of rearward facet. (See Aebi, Figs. 1 and 3). As discussed above, Fraser does not disclose a forward facing facet as recited in independent claim 219. Even if side facets 76 and 78 were considered to be forward facing, Fig. 11 of Fraser shows that the included angle at the peak of the rearward facet

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72 is smaller than the included angle at the peak of each of the opposing side facets 76 and 78.

Applicant submits that the rejection of independent claims 1 and 219 and claims dependent therefrom under 35 U.S.C. § 103(a) as being unpatentable over Aebi in view of Fraser has been overcome.

The Examiner rejected independent claim 219 and dependent claims 228-254, 259-270, and 277-284 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,258,125 to Paul et al. ("Paul") in view of Fraser. Applicant respectfully traverses the rejection at least for the reason that the combination of Paul and Fraser does not result in Applicant's claimed invention as recited in independent claim 219.

The Examiner admitted that "Paul is silent regarding the length of the forward facing facet having a maximum length as measured along a line parallel to the maximum length of the base, the maximum length of the forward facet greater than the maximum length of the base" as recited in independent claim 219. (Office Action, page 5, lines 1-4.) Similarly to Paul and as set forth above on page 16, lines 1-8 above, Fraser does not disclose or suggest a forward facet as recited in independent claim 219. Thus, the combination of Paul and Fraser does not teach or suggest each and every recitation of independent claim 219.

Applicant respectfully submits that contrary to the Examiner's contention, it would not have been obvious to one of ordinary skill in the art to form the rearward facet of Paul in view of Fraser "such that the length of the forward facet is greater than the maximum length of the base such that the projections dig into the bone and better resists [sic] expulsion." (Office Action, page 6, lines 18-21.) Applicant submits that in view of the KSR v. Teleflex guideline set forth above, the Examiner's proposed reasoning to modify the configuration of teeth 12 of Paul in view of Fraser lacks a rational underpinning to support the legal conclusion of obviousness.

Specifically, Fraser teaches a three-faceted projection 18 and does not teach or suggest a four-faceted projection having a forward facet as recited in independent claim 219. Paul teaches pyramid-shaped teeth 12 each having four facets. (Paul,

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col. 3, line 42; FIGS. 1 and 9.) Paul teaches that "the angle formed from the tip to the base [of the teeth] is approximately 60°," or "[a]lternatively, teeth 12 have a saw tooth shape." (Paul, col. 3, lines 43-44.) Paul further teaches that the "initial mechanical stability afforded by teeth 12 minimizes the risk of post-operative expulsion of implant 10." (Paul, col. 3, lines 40-42) (emphasis added). Applicant submits that since Paul expressly teaches that teeth 12 of implant 10 already minimize the risk of expulsion of the implant, it would not be obvious to one of ordinary skill in the art to change the configuration of teeth 12 in view of Fraser to "better resist expulsion" as contended by the Examiner. Moreover, Applicant submits that if projections 12 of Paul were to be modified in view of Fraser to include a rearward facet with a negative slope as proposed by the Examiner, the projections of Paul would be unworkable for their intended purpose at least for the reasons set forth below.

Paul discloses an implant made of allograft bone and teaches that "teeth 12 provide the mechanical interlock by penetrating the end plates" of the vertebrae. (Paul, col. 3, lines 39-40.) In Paul, teeth 12 are made of bone and are configured to penetrate the strong bone of the end plates of the vertebrae. Fraser teaches an implant made of metal or metal-based alloy. (Fraser, col. 7, lines 28-29.) In Fraser, the metal teeth of the implant are sufficiently strong to penetrate the strong bone of the end plates despite having a rearward facet with a negative slope (i.e., a back cut). Applicant submits that if teeth 12 of the bone implant of Paul were modified to include a rearward facet with a negative slope as shown in FIG. 1C of Fraser, the structural integrity of teeth 12 would be reduced.

Specifically, the angle between the sides and the base of teeth 12 would be greatly decreased to reduce the size of the base of the tooth and create an overhang at the peak of the projection. The weakened teeth could break when penetrating the strong bone of the endplates during insertion of the implant. The mechanical interlock between the implant and the vertebrae would be compromised, rendering the implant of Paul unworkable for its intended purpose. Accordingly, Applicant submits that one of ordinary skill in the art would not form the bone projections of Paul with a "back cut" as

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disclosed in Fraser in reference to metallic surface projections. Applicant further submits that the Examiner has not provided any evidence of a known implant having a projection made of bone and having a "back cut."

Applicant submits that the rejection of independent claim 219 and claims dependent therefrom under 35 U.S.C. § 103(a) as being unpatentable over Paul in view of Fraser has been overcome.

Applicant submits that independent claims 1 and 219 are patentable and that dependent claims 3, 5, 19-56, 203, 204, 207-209, 228-254, 259-271, and 277-284 dependent from independent claim 1 or 219, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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